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(54) Surgical Securing Means

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SURGICAL SECURING MEANS

ABSTRACT OF THE DISCLOSURE

Means are provided for use with surgical drapes or towels, by which the surgical drape or towel may be secured to the body of a surgical patient, or by which surgical tubing or other articles may be fixed in place relative to the sterile field on the patient. The securing means, in general, comprises a movable and placeable body -- several are used -- having a lower surface which may be adhesively attached to the body of the surgical patient, and having an upper surface with several protuberances or other portions that extend above the area surrounding them. The securing means are affixed to the body of the patient, and then the surgical drapes or towels may be affixed to the securing means by clamping them thereto, without piercing the drape or towel and thereby assuring that the septic barrier around the sterile field remains unbroken. There is also no trauma to the patient.

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FIELD OF THE INVENTION

This invention relates to means for securing surgical drapes or towels to the body of a surgical patient, and more particularly provides means by which surgical drapes and towels may be secured to the patient without injury to the patient or damage to the bacterial barrier provided by them; and without additional trauma to the patient, beyond that caused by the primary surgical procedure being carried out. The invention also provides a means for securing surgical tubing relative to the field of surgery, in either a moveable or immoveable manner.

BACKGROUND OF THE INVENTION

There have been several general approaches to preparing ("prepping") and draping any particular portion of a surgical patient's body for surgery. Those procedures include the preparation of a sterile field, using surgical drapes or towels, which may or may not be fenestrated, or otherwise, so that the drapes or towels form a sterile field and present a bacterial barrier around the area. Of particular concern to the present invention is the manner by which the surgical drapes or towels are secured in place.

The most usual method by which surgical drapes and/or towels are secured in place relative to the sterile field of the patient's body has been to secure the surgical drapes or

towels to the body by the use of locking forceps which not only pierce the surgical drape or towel, they also pierce the skin of the patient and thereby secure the drape or towel in place relative to the sterile field. That securement is, of course, by the mechanical attachment through the skin and subcutaneous layers of the patient's body. This gives rise to secondary wounds, additional trauma, and possible additional disfigurement to the patient, due to further scarring that may occur.

Moreover, the bacterial barrier which is supposedly presented by the surgical drape or towel is broken due to the piercing action of the pincers through the material of the drape or towel, and after several uses -- as is common when the drapes or towels are made of muslin or other reusable material -- there may be a number of breaks or discontinuities in the otherwise supposedly sterile and secure bacterial barrier.

The other general approach has been the use of adhesive strips or areas which form a part of a surgical drape or towel, for placement on the body of the patient. Generally, however, such drapes or towels have needed to be disposable, as the adhesives will not withstand washing, giving rise to considerable costs of acquisition, and indeed of storage and warehousing. Several prior art examples are particularly to be noted. Each is very expensive, and none of the prior art devices easily permits any readjustment or re-positioning of the surgical drape or towel, once it is placed.

Bayer et al, in U.S. Patent 3,561,440, issued February 9, 1971, teach the use of several tabs of self-adhering adhesive

material which are incorporated into or secured to the material of a disposable surgical drape. However, each of the adhesive areas must have a release paper removed from it, and each forms an integrated part of the total drape that cannot be used with any other drape.

Krzewynski, in U.S. Patent 3,871,369, issued March 18, 1975, shows several embodiments of disposable surgical drapes or towels, all of which require the placement of the drape or towel and thereafter unfolding an edge, to which has been secured an adhesive area having a releasable cover sheet. The particular stated advantage of the Krzewynski device is that correct placement with respect to the sterile field may be assured.

Merry et al, in U.S. Patent 4,080,963, issued March 28, 1978, teach a fenestrated disposable drape which may be unfolded to a number of different configurations. However, as before, the Merry et al device is yet another form of drape, and not a securing means for retaining any drape in a fixed portion.

Stoneback, in U.S. Patent 4,316,456, issued February 23, 1982, teaches a surgical drape system having a fenestrated disposable drape similar to that previously taught by Krzewynski, above. Indeed, Stoneback provides several drapes one above the other, where the fenestration in the top drape is substantially larger than in the bottom, and again creates the problems of expense and re-positioning, discussed above, which is common to all drapes.

While preparing for the surgical process, certain of the

operating room personnel -- at least one surgeon, at least one nurse -- are "sterile" and are permitted to work at the sterile field where the operative wound is to be made. Other persons within the operating room are "non-sterile", and perform such functions as removing soiled sponges, used equipment, etc., away from the sterile area of the operating room. All of these procedures, of course, are established to safeguard the health of the patient, particularly against post-operative infection. However, the risk of infection still exists where the bacterial barrier surrounding the sterile field is broken or is not intact at the time that it is put into place.

According to previous procedures, especially where launderable and reusable surgical drapes and towels are used in order to keep expenses down, the surgical barrier is broken whenever the surgical drape or towel is secured to the patient by piercing the material as well as piercing the skin of the patient. Moreover, previous holes that have been made from previous surgical procedures may, if the material has not been previously patched, result in a broken or non-integral bacterial barrier even before the surgical procedure begins.

The disadvantages mentioned above may be overcome using the securing means for surgical drapes or towels of the present invention. Those disadvantages are particularly overcome because there is no necessity for the material of the surgical drape or towel to be pierced at any time, and yet a secure attachment or placement of the surgical drape or towel with respect to the sterile field is assured.

Moreover, surgical tubing which may enter the sterile

field -- suction tubes or the like -- may also be secured in place with respect to the sterile field, particularly easily using certain embodiments of the securing means of the present invention, as discussed hereafter.

The securing means of the present invention, in its simplest form, comprises an independent, movable and placeable body that may be moved and placed independently of any drape or other similar securing means by the surgeon or sterile nurse as the sterile field is being prepared. Each securing means has a lower surface and an upper surface; and on the lower surface there is an adhesive layer and a releasable cover sheet which is placed thereover. The adhesive layer may be a pressure sensitive adhesive, such as polyacrylate or polymethacrylate, or other approved surgical adhesive materials.

The upper surface of the securing means has at least one portion which has an elevation relative to the lower surface that is above the area which is in the vicinity of that at least one portion. The at least one portion has a thickness and a mechanical strength which is sufficient to accommodate a clamping action thereagainst.

By the provision of such securing means, this invention permits the use of forceps or clamps that do not need to pierce the drape, so that the bacterial barrier surrounding the sterile field will not be broken. Moreover, as the securing means is anchored to the patient by adhesive means, no additional wounds or trauma are caused to the patient.

Thus, this invention provides an inexpensive means for securing surgical drapes or towels around the sterile field,

while assuring integrity of the bacterial barrier without causing additional wounds or trauma to the patient.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and objects of the invention, and several embodiments thereof, are more fully discussed hereafter in association with the accompanying drawings, in which:

Figure 1 is a perspective view, but not to scale, of a first embodiment of a securing means according to this invention;

Figure 2 is a perspective view of a second embodiment of a securing means according to this invention; and

Figure 3 is a perspective view showing two securing means in use for the purpose of maintaining surgical tubing and tools in place.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

As mentioned above, the present invention is directed to securing means for use with surgical drapes or towels, several embodiments of which are illustrated in Figures 1 to 3. Indeed, Figure 2, as discussed hereafter, illustrates one preferred embodiment and suggests an alternative to that embodiment.

In any event, it is to be noted that surgical drapes or towels may be secured to the surgical patient by other means than piercing the drape or towel and piercing the skin of the

patient; or by other means than a self adhesive strip permanently forming a part of a disposable drape or towel. Such alternative means are particularly provided by the present invention, whereby surgical drapes or towels may be used, without damage to them or additional wounds or trauma to the patient.

With reference to Figure 1, there is provided a first embodiment of a securing means for use with surgical drapes or towels, which comprises a body 10 which is independant of any other similar body -- i.e., the securing means are provided (usually packaged in pairs) in such a manner that as many of them may be used as are required, and each of the independent bodies 10 or otherwise is movable and placeable on the surgical patient, irrespective and independant of any other similar body. Each of them comprises a lower surface 12 and an upper 14 surface.

On the lower surface 12, there is provided an adhesive layer 16 which is generally also provided with a releasable cover sheet 18 placed thereover. The releasable cover sheet 18 is removed by the sterile nurse or surgeon at the time that the securing means 10 is placed by him on the patient (or elsewise as described hereafter).

The upper surface 14 of the securing means 10 of the embodiment of Figure 1 has at least one portion, and in this case two portions, designated as 20, each of which has an elevation with respect to the lower surface 12 higher than the area 22 which extends between the portions 20. The area 22 may, as described hereafter with respect to Figure 2, be

considered to be that area of the body 10 which is in the vicinity of each of the portions 20.

The upstanding portions 20 of the securing body 10 of Figure 1 each have a thickness and a mechanical strength which is sufficient to accommodate a clamping action against them. That is, each portion 20 may be clamped against by clamping forceps or pincers, without collapsing or otherwise being destroyed; and each portion has the mechanical strength to withstand the clamping action and to withstand such other reasonable forces as may be imposed on it, such as the weight or a portion of the weight of the surgical drape or towel, either dry or wet.

A different embodiment of securing means for use with surgical drapes or towels, according to the present invention, is shown at 24 in Figure 2. The securing means 24 of Figure 2 has a lower surface 26 having an adhesive layer 28 and releasable cover sheet 30 placed thereover. In the upper surface of the securing means 24 of Figure 2, there are provided a number of protuberances 32. Each of the protuberances or portions 32 may have substantially straight sides as the portions 20 of securing means 10 of Figure 1, or they may have upwardly and inwardly directed sloped sides, as illustrated. There may also be some further portions 34 similar to and contiguous with the portions 32, such that each area 36 which is bounded in part by one of the portions 32 and 34 is lower in elevation relative to the lower surface 26 than the portions or protuberances 32 and 34. The securing means 24 of Figure 2 may therefore have a generally waffled upper

surface.

In utilizing securing means such as those of either Figure 1 or 2 in their primary function, the surgeon or sterile nurse places at least one and usually a plurality of the securing means on the skin of the patient surrounding the area which is to be prepared as the sterile field. Of course, in each case the releasable cover sheet is removed from the lower surface of the securing means and discarded. As the surgical drapes or towels are placed over the body of the surgical patient, it may be necessary for the surgeon or sterile nurse to feel for and determine the positioning of the securing means against the body of the patient, through the surgical drape or towel. However, the protuberances 20, 32 or 34 have a sufficiently high elevation above the lower surface by which they are secured to the patient, so that they may be easily located. Thereafter, clamping forceps or other clamps or pincers may be used to secure the surgical drapes or towels in place, relative to the sterile field where the surgical wound will be made, without piercing the surgical drape or towel, and of course without piercing the skin of the patient. Thus, no permanent damage is done to the surgical drape or towel, and no damage or trauma to the patient occurs.

In another function that the securing means of the present invention serves, as illustrated in Figure 3, surgical tubing or other devices or implements may be secured in place relative to the sterile field by securing means according to the present invention. For those purposes, securing means 10 as shown previously in Figure 1 and discussed above, are particularly

useful.

In Figure 3, a surgical drape or towel 38 is shown overlying a portion 40 of the patient's body, and has been placed and secured using other securing means according to the present invention. A pair of securing means 10A are placed on the surgical drape 38 in superimposed relation one to the other, such that the lower securing means 10A is secured by its adhesive coating to the surgical drape or towel 38.

When the areas of the upper securing means or body 10A are stripped of their releasable cover sheet, the two bodies may be superimposed one on the other, with the upper body adhesively secured to the lower body at the upper surface of its portions 20A. However, before the upper body is placed or superimposed over the lower body, surgical tubing 42 and 44 -- such as suction tubes or the like -- are placed between the protuberances 20A of the lower body 10A, so that they may be held and secured in place by the placement of the upper body 10A over the lower body 10A.

Also shown in Figure 3 is a further purpose for the securing means of the present invention. It may sometimes happen that the surgeon wishes to put down a surgical implement, such as a forceps 46, without taking them away from the surgical field, and in that case the thumb or finger hole 48 (or other convenient part of an implement) may be easily placed over one of the protuberances 20 of any one of the securing means 10 in use.

The materials from which the securing means of the present invention may be formed include both woven and unwoven

materials, which may be folded and/or stitched in place, particularly as shown in Figure 2; or closed-cell or open-cell foam material, such as polyethylene, polypropylene, polyurathane and polyvinyl chloride.

Other embodiments of securing means according to the present invention may be formed, and other materials used, without departing from the spirit and scope of the appended claims.

CLAIMS

1. Securing means for use with surgical drapes or towels, comprising an independent, moveable and placeable body having a lower surface and an upper surface;

said lower surface having an adhesive layer and a releasable cover sheet placed thereover;

and said upper surface having at least one portion thereof which is higher in elevation relative to said lower surface than the contiguous area of said upper surface which is in the immediate vicinity of said at least one portion.

said at least one portion having a thickness and mechanical strength sufficient to accommodate a clamping action thereagainst.

2. The securing means of claim 1, where said upper surface comprises a plurality of portions, each of which is higher in elevation relative to said lower surface than the contiguous area of the upper surface in its respective vicinity, and each having a thickness and mechanical strength sufficient to accommodate a clamping action thereagainst.

3. The securing means of claim 1 or 2, where said upper surface has at least two spaced apart portions, each having a substantially planar top surface which is higher in elevation relative to said lower surface than the contiguous area of the upper surface in the immediate vicinity of each of said spaced apart portions;

and where said releasable cover sheet on said lower surface is removable to effect adhesive connection between the respective upper and lower surfaces when two of said bodies are placed in superimposed relation one to the other.

4. The securing means of claim 1 or 2, where said body above said adhesive layer is formed of a material chosen from the group consisting of woven or non-woven material, and closed-cell or open-cell foam material.

5. The securing means of claim 1 or 2, having at least first and second portions in said upper surface, that are contiguous one with the other, where the area bounded in part by said first and second portions is lower in elevation relative to said lower surface than said first and second portions.

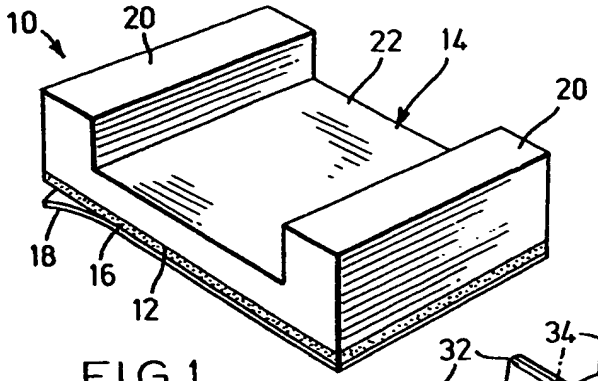

FIG.1

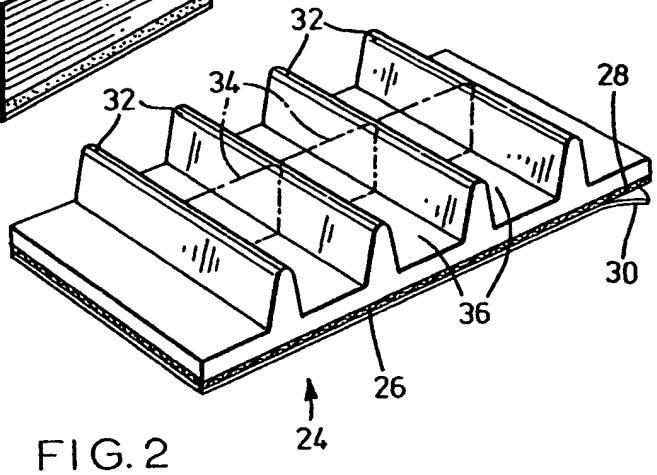

FIG.2

FIG.3